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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,419	12/13/2001	Audrey Goddard	P2637-1	5267

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GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/09/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,419

Applicant(s)

GODDARD ET AL.

Examiner

Janet L. Andres

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-23 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other:

Art.Unit: 1646

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group IV, methods of treatment in Paper No. 8 is acknowledged. Claims 1-30 are pending in this application. Claims 1-18 and 24-26 are withdrawn from consideration as being drawn to a non-elected invention.

Priority

2. The nature of the priority claim in the first line of the specification is unclear. It is appears that the instant application claims priority to PCT/US00/05601, PCT/US01/19692, and PCT/US01/21735 and that PCT/US00/05601 claims priority to 60/132379; however clarification of the first line of the specification is requested. Also, the nature of the priority claim (continuation, continuation-in-part) must be specified; see the OG notices of 18 March 2003.

Specification

3. The title of the invention is not descriptive. Novelty is a legal concept and does not describe the invention claimed. Novelty is required of all claimed inventions before they are issued as patents. To use the term in the title would imply merit in this regard without actual examination. Accordingly, though MPEP 606.01 does not specifically refer to "novel", it is similar to the term "improve" which also implies merit without examination.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1646

5. Claims 19-23 and 27-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

6. The instant claims are drawn to methods using the PRO4425 polypeptide to promote the growth of bone or cartilage and thus to treat disease, or, alternatively, to methods using inhibitors of the PRO4425 polypeptide to inhibit bone growth and thus treat disease. Thus, what is required is that PRO4425 be osteogenic or chondrogenic, and further that it be expressed and active post-natally, so that inhibition of its action would be expected to affect disease linked to overgrowth of bone. What is provided in the specification, however, is evidence of expression in the developing embryo (p. 68, lines 10-22). While, as Applicant indicates, this expression suggests an involvement in the development of bone and cartilage, it provides no guidance as to how the polypeptide is involved. Development is a complex process involving such factors as migration, proliferation, differentiation, apoptosis, and the production of extracellular matrix. Thus, the mere presentation of specific expression in embryogenesis is not sufficient direction as to how one of skill in the art could use the polypeptide, or inhibitors thereof, to affect disease.

Art Unit: 1646

Applicant has provided no teachings to indicate that the protein is in fact osteogenic or chondrogenic, nor has Applicant provided any teachings to indicate that the protein is active in any disease. Further, the art fails to provide support for such methods. For example, U.S. patent application 2003/0036114, which has an inventor in common with the instant application, teaches that the PRO4425 affects glucose uptake (experiment 38) and mesangial cell differentiation (experiment 41) but is silent as to its effects in a chondroproliferative assay (experiment 36). Thus, without further guidance as to the function of PRO4425 and its role in bone disease that would allow one of skill in the art to predictably use it, or its inhibitors, to affect bone and cartilage growth, it would require undue experimentation to practice the invention as claimed.

7. Claims 19-23 and 27-30 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims encompass all polypeptides that could be identified as PRO4425, as well as all agonists and antagonists. PRO4425, as described on pp. 5-6, encompasses homologs and fragments of PRO4425. The claims thus encompass a genus of PRO4425 molecules, and further encompass molecules having a related function, and molecules antagonizing that function. However, Applicant has not described "relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying

Art Unit: 1646

characteristics, sufficient to show the applicant was in possession of the claimed genus” of PRO4425 polypeptides, PRO4425 agonists, or PRO4425 inhibitors. See MPEP§ 2103 and *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. There are no structural features essential to PRO4425 set forth, nor is there any description of functional characteristics associated with any structure. Thus one of skill in the art would be unable to identify PRO4425-related molecules that had the characteristics of the parent, and would also be unable to identify other agonists and antagonists of such molecules. The invention is therefore not described in the specification so as to convey to one skilled in the art that Applicant was in possession of methods using such molecules.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that

Art Unit: 1646

sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Daniel Andres, Ph.D.

July 8, 2003